



December 9, 2013

Ono Pharmaceutical Co., Ltd.  
OncoTherapy Science, Inc.

**Clinical Trial Application submitted for Phase I study of ONO-7268MX2,  
peptide-cocktail vaccine for hepatocellular carcinoma**

Ono Pharmaceutical Co., Ltd (Head office: Chuo-ku, Osaka, President and Representative Director: Gyo Sagara, "Ono") today announced that Ono has submitted Clinical Trial Application for Phase I study for ONO-7268MX2, a product containing in-licensed peptide vaccines for hepatocellular carcinoma. The vaccines were in-licensed from OncoTherapy Science Inc. (Head office: Kawasaki-city, President & CEO: Takuya Tsunoda).

The aim of this clinical study is to evaluate safety and immune response when ONO-7268MX2 is administered to hepatocellular carcinoma patients who are refractory or intolerant to standard therapies.

Hepatocellular carcinoma accounts for 90% of primary hepatic cancer in Japan<sup>1)</sup> and approximately 30 thousands patients reportedly die annually<sup>2)</sup>. Meanwhile, as treatments for hepatocellular carcinoma, surgical treatments such as hepatic resection, radiofrequency ablation and/or percutaneous ethanol injection are performed as well as chemotherapy and/or radiotherapy, however the prognosis is still poor and novel treatment has been desired.

ONO-7268MX2 is a cocktail vaccine which contains multiple epitope peptides derived from oncoantigens specifically expressed in hepatocellular carcinoma as active ingredients, and is strongly expected to show anti-tumor activity by inducing the cytotoxic T cells specific to hepatocellular carcinoma. This clinical study is going to evaluate the safety of ONO-7268MX2 as well as the immune response induced by the vaccine and will lead to the subsequent phase of the clinical study.

- 1) Liver Cancer Study Group of Japan. Report of the 18th Nationwide Follow-up Survey of Primary Liver Cancer in Japan (2004 – 2005). 2009
- 2) Foundation for Promotion of Cancer Research. Cancer statistics in Japan-2012.

**Contacts**

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